

Crompton

Uniroyal Chemical

REGISTRATION SECTION

June 13, 2002

Public Information Resources and Records
Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 119, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Response to Propargite RED: Docket Control No. OPP-2-002-0009

To Whom it May Concern:

Enclosed is the Uniroyal Chemical Company response to the Reregistration Eligibility Document (RED) for propargite. There are also 4 copies (one for the docket) of a ^{14}C Study on the magnitude of radioactive residues following post-harvest use on peaches. Uniroyal requests assignment of an MRID number for this study. We understand from conversations with the Agency that we are to address the requirements to conduct specific studies in our responses to the Generic and End-use Data Call In Notices. As of this date, Uniroyal has received neither the DCIs nor a copy of the RED from the Agency. Comments herein apply to the RED obtained from the EPA web site.

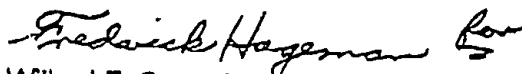
The attached response includes what we believe to be errors that occur in the document, several items that we believe should be addressed in a different fashion, and changes in the label that Uniroyal believes to be beneficial to growers and to protection of the environment. We do not have major differences with the content of the RED. Should we find other items that we believe should be corrected, we will bring these to the Agency's attention.

As directed, Uniroyal is now discussing required label changes with the Product Manager. We understand that we will have 8 months from the date marked on the RED to be sent Uniroyal to submit labels with all required changes.

Should you have any questions regarding this response, please contact Mr. Fred Hageman at (203) 393-2163.

Sincerely,

UNIROYAL CHEMICAL



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Encl.
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TRANSMITTAL BIBLIOGRAPHY

DATE: JUNE 13, 2002
REFERENCE: Response to Propargite RED
PRODUCT: All Registered Propargite Products

MRID No. (by EPA)	Vol. No.	Guideline Ref. No.	Citation
NA	1	NA	Uniroyal Chemical Company. (June 13, 2002) Response to Propargite RED. No project number. An unpublished report prepared at Uniroyal Chemical Company, Bethany, CT. 6 pages.
	2	860.1000 860.1500	 [Residue] Gay, M.H. (June 5, 2002) ¹⁴ C-Omite-30WS on Peaches: Magnitude of the Radioactive Residues Following Post- Harvest Use. Project No. 99189. An unpublished study report prepared at Uniroyal Chemical Company, Middlebury, CT. 92 pages.

Uniroyal Chemical Company Response to Propargite RED

6/13/02

RESTRICTED ENTRY INTERVALS

During the RED process, Uniroyal Chemical proposed specific REI exceptions and a small number of reduced REI's for specific tasks that are supported by data generated for EPA by industry's Agricultural Recntry Task Force. In the Federal Register notice, EPA declined to include most of these suggested exceptions in the RED but stated that the Agency would consider proposals to include specific REI exceptions supported by evidence of need during the 60-day public comment period. EPA also, as seen below, granted several task specific REIs in the RED. Both data support and need continues to exist for these REIs. They are listed below by crop. (Note that the exceptions for scouting and irrigation are for tasks not covered by existing exceptions to the WPS.)

Almonds:

Current REI = 7 days

New REI = 22 days

Uniroyal proposed exception: 1 day for hand weeding

Beans, dry:

Current REI = 7 days

REI = 9 days

Uniroyal proposed exception: 1 day for hand weeding and thinning

Carrot (grown for seed):

Current REI = 7 days

Proposed REI = 2 days (3 days in arid areas)

Exception: hand harvesting will be 13 days

Uniroyal proposed exception: 1 day for hand weeding and thinning

Clover (grown for seed):

Current REI = 7 days

Proposed REI = 9 days

Uniroyal proposed exception: 1 day for hand weeding and thinning

Corn (field, pop, sweet):

Current REI = 7 days

New REI = 13 days

Uniroyal proposed exceptions: 1 day for scouting and irrigation, hand weeding and thinning

Cotton:

Current REI = 7 days

New REI = 6 days

Uniroyal proposed exception: 1 day for scouting and irrigation, hand weeding and thinning

Citrus:

Current REI = 28 days

New REI = 36 days

Exception: 20 days for pruning

Uniroyal proposed exception: 2 day for irrigation and hand weeding.

Wine Grapes/Raisin Grapes:

Current REI = 14 days

New REI = 16 days

Uniroyal proposed exception: 1 day for pruning, irrigation, scouting, and hand weeding

Table Grapes:

Current REI = 21 days

Current exception: 42 days for turning canes

New REI = 16 days

New exception: 27 days for turning canes

Uniroyal proposed exception: 1 day for pruning, irrigation, scouting, and hand weeding

Hops:

Current REI = 7 days

New REI = 21 days

Exception: 30 days where special local need labels allow application at 1.9 lb ai/A

Uniroyal proposed exception: 1 day for irrigation, scouting, and weeding

Nectarine:

Current REI = 7 days

New REI = 5 days

Uniroyal proposed exception: 1 day for irrigation and hand weeding

Walnuts:

Current REI = 7 days

New REI = 30 days

Uniroyal proposed exceptions: 1 day for shaking, irrigation and hand weeding

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Please note that the above crop-specific list of REI exceptions can be concisely summarized on product labeling. In addition to listing REIs in tables with PHIs, re-entry restrictions can be encapsulated in the following manner:

- * Professional Crop Advisors are permitted by WPS to determine any necessary early entry PPE for themselves and immediate supervisees performing scouting activities.
- * Early entry PPE is not required for irrigation tasks that involve no contact with soil or foliage.
- * All scouting and irrigation activities may be performed in tree crops, corn, cotton, and hops at one day after treatment with OMITE (two days for citrus).
- * Pruning may occur at 21 days REI in citrus, at 7 days in non-bearing trees, and at 3 days in stone fruit.
- * Transplanting, hand weeding, and thinning of immature plants may occur at 1 day following treatment with OMITE/COMITE (two days for citrus).
- * Almond shaking and irrigation are noted in the RED as falling under WPS no contact exemptions. Uniroyal will submit labels noting this fact.

These REIs are justified on the basis of general agronomic practices, data currently available, and pre-established policy. Specifically, the rationale is as follows:

-- HED has called in several million dollars of crop reentry data from industry, and actually the majority of this is on low and medium- exposure activities. The nature of these data was conceived by the Joint Regulatory Task Force Technical Committee, which included USEPA, CDPR, and PMRA, to enable establishment of activity-specific REIs. We should take the opportunity to do this, if the data allow, and utilize those resources.

-- HED risk assessors have been trained to do activity-specific analysis because the science of determining exposure is refined enough to permit such a framework. Such a thorough analysis was completed for propargite. The effort required of the assessors to thoroughly understand exposure in different activities should be considered.

- The framework HED uses was determined in large part based on ARTF survey data. The industry task force largely identified the activities that comprise the different exposure levels in the HED assessment framework. The fact that these activities were identified in communications with thousands of growers is reasonable evidence that the activities are performed and are of commercial importance.
- Conference calls with stakeholders proceeded under the assumption that all of the REIs identified in the assessment would be used. Changing that assumption would require re-involvement of all stakeholders to preserve transparency and cooperation.
- At least 60 to 80 potential reentry scenarios were considered in the proposed exceptions. A request to submit agronomic justification for each specific activity

exception (i.e. one crop-activity combination) does not recognize the kind of effort this would require. A key reason for the ARTF growers survey was to enable everyone to gain access to the best possible real world agronomic data through the breadth of its sampling.

- The proposed general REI exceptions, approximately five, are a concise translation of the analysis of potentially dozens of scenarios. Rather than an over-complication, these few sentences clarify regulation and allow us to take full advantage of the assessment for whatever economic benefits there may be to the user. The exceptions will not appear in their entirety on every label because each label concerns only a subset of registered crops.
- Exceptions generally concern lower-exposure activities. The standards of data quality and quantity for regulating these activities should not be made higher than for many higher exposure activities, particularly since resources for post-application research in residue transfer have been allocated fairly evenly.

CORRECTIONS TO RED LABEL CHANGES

Beans: The rate on beans should be (based on previous discussions with the Agency, 4.1 pts. of Comite (#400-104), or 5 pints ai/A, not the 3.7 pts. Comite, or 4.5 lbs. ai/A, listed.

Corn: Field corn and popcorn have the wrong application rate. With 2.5 lbs. ai/A, the desired rate, the Comite (#400-104) use rate should be 3 pts. /A and for Comite II (#400-154) 3.375 pts. /A.

Potatoes: Comite rate is 4.1 lbs./A (see below) not 4.9 lbs./A.

POST-HARVEST ISSUE

During, and as a part of, the RED process, Uniroyal requested that EPA reinstate the post-harvest use on stone fruit. Subsequently, in the final RED, EPA recalculated cancer risk using a more appropriate model. As previously stated to EPA, had the Agency and Uniroyal known in advance the great need for the post-harvest stone-fruit uses, as expressed by many growers and commodity groups, compared to the low risk, this use may not have been voluntarily cancelled.

Uniroyal is submitting with this response a C14 study on the magnitude of residues in/on post harvest peaches. The total radioactive residue (TRR) as a result of two sequential applications of a typical end-use product (Omite-30WS, #400-427) using the maximum application rate was 1.28 +/- 33.6 ppb as propargite equivalents. Even though this level of residue would represent a negligible addition to dietary risk even if it were propargite, Uniroyal is now verifying that this low TRR does not represent the presence of propargite. A study will be submitted in the very near future to demonstrate this. We plan to add the stone fruit post harvest use to the several of the formulated product labels which will be submitted with mandated changes for Agency approval within 8 months of the date of the RED.

ERRONEOUS REQUIRED STATEMENTS

Uniroyal detected in the document what we believe to be several errors regarding required statements. These are:

- The RED presents the statement "Mixers and loaders supporting applications to corn and cotton must use a closed system that -----". During the RED discussions between the Agency and Uniroyal, however, it was established that the closed system was to apply to mixers and loaders using aerial application only for corn and cotton.
- The RED specifies the following sentence to be added to the new spray drift statement, "Do not allow this product to drift off target site". Similar to the above statement, in discussions with Uniroyal prior to issuance of the RED, EPA stated that they had determined that this statement should not be added to the propargite end-use labels. Even though the RED states that this is a temporary addition until the proper wording is developed, Uniroyal remains concerned about liability resulting from this unenforceable statement. In addition, the current label has, and the RED specifies, another more appropriate statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

ERROR IN TEXT

On page 14, under "e. Food Risk Characterization" the text refers to "----developmental effects (birth defects) in rats were noted in one developmental rat toxicity study." The reference should clearly, based upon Table 2 on that page, be to rabbits tested in a rabbit developmental toxicity study.

UNIROYAL REQUESTED CHANGES

The following changes are consistent with the RED determinations as to appropriate REIs and rates:

Mint: Request for 7-day REI based on reduction of rates

Currently, the labeled application rate for Omite-6E (Reg. No. 400-89) on mint is a maximum of 3 pints of product or 2.45 lb. AI/acre. EPA correctly used this rate in setting an REI of 9 days. However, the propargite product used by the vast majority of growers is Comite (reg. No. 400-104) where the mint use is on a number of Section 18 labels. The use rate on these SLNs is 2.5 pints or 2.04 lb. AI/acre. It has come to our attention that the 9-day REI would result in crop loss because many growers must reenter at 7 days for irrigation scheduling purposes. To rectify the situation, Uniroyal will submit to the Product Manager an Omite-6E label with the maximum rate reduced to 2 ¾ pints. In addition, with approval of the product manager, we are incorporating the Comite SLNs

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into the Section 3 label. The reduced rate will support the 7-day REI needed by mint growers using wheel-line and hand-line irrigation systems. We therefore request EPA to set a 7-day REI in mint for propargite products.

Potatoes: Correction of required rate

Uniroyal wishes to remove this use from the Omite 6E (#400-89) label and keep a 5-pint maximum ($2\frac{1}{2}$ plus $2\frac{1}{2}$ pts) on the Comite label (#400-104). Five (5) pints Comite are equal to 4.1 lbs. ai/A while the current $5\frac{1}{2}$ pint rate for Omite-6E also equals 4.1 lbs. ai/A.